

A comparison of sea-cucumber based gel to conventional hydrogels in wound healing

Submission date 11/01/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/02/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/10/2018	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Gamat (sea cucumber) has been widely used as a traditional medication/supplement for various ailments in South-east Asia, e.g. Malaysia, Indonesia, Thailand, Philippines and China. Gamat extracts contain many nutrients which may play a role in tissue repair, and they have been tested in rats and as a toothpaste in humans. However, to date, there have been no studies on human wounds. The aim of this study is to assess the effectiveness of Gamat gel in comparison with hydrogel in the treatment of skin graft donor sites.

Who can participate?

Patients with partial thickness wounds created as an after effect of skin graft harvesting

What does the study involve?

Both gels are applied to the patient simultaneously on the same wound divided into two areas. The duration of treatment is 10-14 days with follow up at day 21, then at 6 to 9 weeks. The effect is judged as which wound heals more on a specific day. Pain tolerance, itch tolerance, and scar quality are also assessed on both wound surfaces.

What are the possible benefits and risks of participating?

The results could show whether Gamat gel heals human cutaneous wounds faster or better. The risks would be allergic reactions, but these have not been reported so far.

Where is the study run from?

Hospital Universiti Sains Malaysia (Malaysia)

When is the study starting and how long is it expected to run for?

August 2016 to September 2017

Who is funding the study?

Universiti Kebangsaan Malaysia (Malaysia)

Who is the main contact?

Dr Adzim Poh Yuen Wen

Contact information

Type(s)

Public

Contact name

Dr Adzim Poh Yuen Wen

ORCID ID

<http://orcid.org/0000-0002-0903-6152>

Contact details

A-3-3, Laman Baiduri,
Jalan SS12/1, Wangsa Baiduri
Subang Jaya
Malaysia
47500

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

USM/JEPeM/16060218

Study information

Scientific Title

A prospective case-control comparative study to evaluate the efficacy of Gamat gel in comparison with hydrogel in treatment of skin graft donor sites

Study objectives

Null hypothesis: There is a no significant difference in the rate of epithelialization between Gamat gel dressing and Duoderm® Hydroactive® Gel dressing on skin graft donor sites.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local ethics board in Hospital Universiti Sains Malaysia (JEPeM), 21/11/2016, ref: USM/JEPeM/16060218

Study design

Single-center prospective single-blinded comparative study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Skin graft donor site wounds

Interventions

This is a prospective, single-blinded, comparative clinical trial involving patients in Hospital Universiti Sains Malaysia with partial thickness wounds which were created as an after effect of skin graft harvesting. Any patient requiring skin grafting and fulfilling the inclusion/exclusion criteria will be approached preoperatively for recruitment. Both gels (sea-cucumber based gel and Duoderm (r) gel) will be applied on the patient simultaneously on the same wound, which is geometrically divided into two areas correspondingly. The effect is judged as which wound epithelializes more on a specific day. Pain tolerance, itch tolerance, and scar quality are also assessed on both wound surfaces. Duration of treatment 10-14 days. Follow up at day 21, then at 6 to 9 weeks.

Intervention Type

Other

Primary outcome measure

Wound epithelialization, assessed by clinical judgment and calculated as percent of surface of wound epithelialized at day 10, 14 and 21 after intervention

Secondary outcome measures

1. Pain and pruritus assessed with visual analogue scale at day 10, 14 and 21
2. Scar quality assessed with modified Vancouver scar scale (MVSS) at follow up (week 6 to 9)

Overall study start date

01/08/2016

Completion date

04/09/2017

Eligibility**Key inclusion criteria**

1. All patients with partial thickness wounds after split-skin graft harvesting
2. This thickness is at 0.2 mm (0.008 inch); harvested with a specified dermatome
3. Skin-graft donors > 25cm² wide
4. Consented patients
5. Patients compliant to the treatment protocol

Participant type(s)

Patient

Age group

Mixed

Sex

Both

Target number of participants

25

Key exclusion criteria

1. Accidental full thickness harvesting
2. Non-compliant patient, causing dressing to dislodge
3. Patients with history of allergy to seafood/ sea cucumber
4. Patients with uncontrolled diabetes mellitus, on steroid medications or who are immunocompromised
5. Pregnancy
6. Patient with skin pathology (eczema etc)

Date of first enrolment

29/12/2016

Date of final enrolment

03/07/2017

Locations**Countries of recruitment**

Malaysia

Study participating centre

Hospital Universiti Sains Malaysia

Department of Reconstructive Sciences

Kubang Kerian, Kelantan

Malaysia

16150

Sponsor information

Organisation

Hospital Universiti Sains Malaysia

Sponsor details

Department of Reconstruction Sciences
Universiti Sains Malaysia, Kubang Kerian
Kelantan
Kota Bharu
Malaysia
16150

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/0090j2029>

Funder(s)**Funder type**

University/education

Funder Name

Universiti Kebangsaan Malaysia

Alternative Name(s)

Universiti Kebangsaan Malaysia (UKM), Universiti Kebangsaan Malaysia (UKM), Malaysia, ukminsta, Universiti Kebangsaan Malaysia - UKM, Universiti Kebangsaan Malaysia (Malaysia), University Kebangsaan (Malaysia), UKM

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Malaysia

Results and Publications**Publication and dissemination plan**

To submit to BioMed Central Complementary and Alternative Medicine Journal.

Intention to publish date

18/03/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Adzim Poh Yuen Wen. A copy of the raw data has been submitted to the Medical Sciences Studies Centre (or Pusat Pengajian Sains Perubatan [PPSP]) of Hospital Universiti Sains Malaysia. All patients were assigned a coded number to protect anonymity.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2018		Yes	No